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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,182	12/14/2001	Steven M. Bowman	022956-0074	1527

21125 7590 11/26/2004
NUTTER MCCLENNEN & FISH LLP
WORLD TRADE CENTER WEST
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2604

EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/022,182

Applicant(s)

BOWMAN ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 16-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 16-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>05/21/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of Terminal Disclaimer, amendment and remarks filed 07/29/04 and IDS filed 05/21/04.

Double Patenting

The terminal disclaimers submitted by applicants overcome the double patenting rejection. However, the following rejection below is made.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 7 and 8 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites "cell types." It is not clear what cells are included or encompassed by the "type." Is the biological component a cell? If the biological component is a specific cell, the specific cell may be recited in place of "cell type"?

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

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patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 5, 7, 8 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Seare, Jr. (US 5,589,176).

Seare, Jr. discloses porous medical device that comprises continuously interconnected pores, which utilizes at least one removable open-cell porous mold form (abstract). The porous medical device can be implanted in the body to promote new loose tissue and new vessel ingrowth (column 3, lines 41-45). The porous medical device can be a breast implant made of polymethacrylate and formed with the desired curvature (column 12, lines 29-36). The porous medical device can also be a drug delivery system for implantation and some of the drugs that may be incorporated are antibiotics (column 14, lines 26-40). Polyglycolic acid or polylactic acid material (column 15, lines 9 and 10) may be used as the polymer for the implant. Tissue such as bone marrow, liver, pancreas, collagen and tissue cell can be transplanted (column 9, lines 41-45) with the aid of the medical device of Seare, Jr.

The instant method of treating tissue injury comprises providing biocompatible, bioabsorbable polymeric foam. The device of Seare, Jr. is administered to the desired site and the device also assumes the structure of the site or target of interest. While Seare, Jr. does not specifically use the term foam, the disclosure that the device is porous and of an open-cell structure implies a structure that is a foam. Seare, Jr. meets the limitations of the claims.

5. Claims 1, 2, 5, 7, 8 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Polson et al. (US 5,487,897).

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Polson discloses a foamed composition (abstract; column 4, lines 43-55; columns 7 and 8) that comprises polyesters (column 6, lines 10-22 and claim 30) and biologically active agent that include antibacterial agents, antifungal agents, anti-inflammatory agents, anti-neoplastic agent and growth factors (column 10, lines 12-43). The disclosure of Polson meets the limitation of the claims.

6. Claims 1-8 and 16-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Vyakarnam et al. (US 6,306,424)

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Vyakarnam discloses administration of a composition for tissue repair and regeneration (column 1, lines 8-14). Vyakarnam's composition comprises a foamed composition that is comprised of biocompatible and bioabsorbable polymer foam and where the biocompatible foam has interconnecting pores and comprises polyesters; and the composition comprises active agents selected from anti-infective, hormones, analgesics, anti-inflammatory agents, growths factors, chemotherapeutic agents, anti rejection agents, prostaglandins and combinations (claims 1-39 and the whole document).

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Felt et al. (US 6,306,177) discloses a system for repairing tissue in situ (abstract;

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columns 7 and 8; column 11, lines 1-7; column 25, lines 31-38). MacPhee et al. (US 6,197,325) discloses method of repairing tissues by administering sealant compositions (abstract).

8. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

